## DRAWING AMENDMENTS

There are no amendments to the drawings.

## REMARKS

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|---|---|
| The following claims were pending in the application: | 1 – 19 and 94 - 111 |
| The following claims have been amended: | N/A |
| The following claims have been cancelled without prejudice: | 20 - 93 |
| The following claims have been added: | N/A |

As a result of the foregoing Amendment, the following claims remain pending in the application: 1 – 19 and 94 – 111.

## RESPONSE TO CLAIM OBJECTIONS

**The Rejections under 35 U.S.C. § 112**

The Examiner has rejected claims 1-19 and 94-111 under 35 U.S.C. § 112, first paragraph, reasoning

> There is clearly a lack of direction or guidance for obtaining an algorithm for determining the amount of the coliform and E.coli where light ratios are used. A great amount of experimentation would be required to apply numerous mathematical modeling techniques for deriving suitable algorithms, as suggested in paragraph 172, page 26-27.
>
> Even if the claims were amended to recite a method of determining the amount of coliform and E. coli in water from light reflected therefrom, the claims broadly indicate that the algorithms includes the amounts of light in at least two of the wavelength ranges (claim 1). However, the algorithms are derived from a multiple regression model that is generated by using a step-wise linear regression model, with a Durbin-Watson statistical test for autocorrelation (page 22). Moreover, the amount of light at each wavelength is one that has been corrected for atmospheric haze and sensor additive offset. Clearly the algorithms used in the instant claims are limited solely to algorithms derived in such a manner, where the amount of light is corrected. There is lack of guidance for determining suitable algorithms in any other manner,

> and this in turn results in a great amount of experimentation to apply numerous mathematical modeling techniques.

Applicant respectfully submits that no undue experimentation is necessary to obtain the relevant algorithms. Anticipating that a wide variety of spectrophotometers capturing a variety of wavelength ranges, including those borne on a variety of satellites, might be applied in the present invention, the specification provides clear guidance for the development of other efficacious algorithms other than the concrete examples provided. In this regard, the original specification teaches *developing* an algorithm through linear regression analysis and is not simply an invitation to experiment. Specifically:

> The invention also includes a method of developing an apparatus for determining the presence of coliform bacterian in water from light reflected therefrom, the device comprising (a) obtaining a measurement of reflected light from the water, the measurement comprising a measurement of the respective amount of light of at least two frequencies; (b) *developing an algorithm relating the respective amounts of light in the at least two frequencies to the amount of coliform bacteria in the water through linear regression analysis*; (c) producing a processor capable of relating the approximate number of the coliform in the water to the respective amounts of light by applying an algorithm...

(See the Specification at Paragraph 0024; emphasis added). Further, the specification describes concrete examples of the use of linear regression analysis used for each wavelength to obtain the most robust and preferred embodiment of the algorithm, as follows:

[0069] For instance, band 2 of the LANDSAT 7 version of the TM sensor (called ETM+) has wavelength limits of 0.53-0.61 μm, band 3 has limits of 0.63-0.69 μm, and band 4 has limits of 0.78-0.90 μm. When mapping phycocyanin pigment, coliform bacteria, and E. coli bacteria in Lake Erie and its tributaries with LANDSAT 7 data, it had to be determined which or how many of bands 1-5 and 7 (which have 30-m spatial resolution and relatively narrow spectral bands, as opposed to the 60-m spatial resolution of band 6 and the relatively wide band-width of the 15-m-resolution band 8) to use. A mathematical procedure (multiple regressions) was applied to seek the best combinations of those bands to correlate with each one of these targets (phycocyanin, coliform, and E. coli) separately. It was determined that the use of the single band radiances (even if they were reduced to spectral reflectances from theoretical atmospheric models) as inputs to this procedure, the resulting algorithm would not be very robust (i.e., repeatable under different solar illumination and atmospheric conditions). Therefore, spectral ratios (ratios of spectral bands, after empirical correction for

> atmospheric haze through a process referred to as "dark object **subtraction**" were input to the mathematical procedure for each pixel from which a water sample had been collected. These 15 non-reciprocal ratios (R21, R31, R32, R41, .....R75) became the dependent variables and phycocyanin (or coliform or E. coli) became the independent variable, which was the result of lab analysis of the water samples. For the LANDSAT 7 overpass, 30 water samples were collected, which were measured for both phycocyanin and coliform content. The best subsets of spectral ratios were determined, and then the ones with the highest $R^2$ (Adjusted) values were tested to see if they passed the Durbin-Watson test. The model with the highest $R^2$ (Adjusted) that also passed the Durbin-Watson test was the model that was considered to be the best.

(See Specification at Paragraph 0069). Accordingly, the specification clearly teaches and describes the development of such an algorithm as described in the present claims, such that the full scope of the invention as reflected in the currently pending claims is fairly enabled without need for undue experimentation. Applicant respectfully submits that the specification provides clear guidance that allows one of ordinary skill to make and use systems, and practice methods, of the present invention. Accordingly, claims 38-46 are enabled and described in accordance with the requirements of 35 U.S.C. §112, first paragraph.

The Examiner Has Not Met the Burden to Establish Undue Experimentation

Applicant respectfully submits that the Examiner has not met its burden regarding undue experimentation. *In re Wands* states:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicant submits that the Examiner has not addressed each of these factors and that the Examiner's rejection falls short of shifting the burden to Applicant.

1. Quantity of Experimentation

"In calling into question the enablement of an applicant's disclosure, the examiner has the initial burden of advancing acceptable reasoning inconsistent with enablement so as to shift the burden to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation." *Ex Parte Douglas W. Akers* (BPAI 2008-6187). An examiner must adequately explain or show that details at issue could not have been determined by a person of ordinary skill in the art without undue experimentation. *Id.*

"The threshold issue is whether the Examiner has met his initial burden of providing a reasonable explanation as to why" a specification is not enabling. Ex parte Liu et al. (BPAI 2009-15302). Further, the standard for determining whether a specification meets the enabling requirement is whether the experimentation needed to practice the invention undue or unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation...the test of enablement is not whether any experimentation is necessary, but whether if experimentation is necessary, it is undue." MPEP 2164.01. Therefore, even a

*considerable amount* of experimentation is permissible if it is routine or if the specification provides a *reasonable amount of guidance* with respect to the direction in which the experimentation should proceed. *Ex Parte Liu*.

The Examiner has noted to "a great amount of experimentation would be required to apply numerous mathematical modeling techniques for deriving suitable algorithms, as suggested in paragraph 172, page 26-27." Applicant respectfully submits that, although not the case here, even if a great amount of experimentation were necessary, that does not mean that the specification is nonenabling, since even "a considerable amount" of experimentation is permissible under the inquiry for determining whether a specification is enabling. Applicant has provided several working examples of the present invention and provided much guidance as to the linear regression process and formulae to be used to arrive at the algorithms claimed in the application.

2. The Amount of Direction or Guidance Presented

The Examiner has not factored in the amount of direction and guidance presented in the specification. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art. MPEP 2164.03. Applicant has, in fact, provided a great deal of direction and guidance regarding developing an algorithm through linear regression. Applicant submits that linear regression analysis is a well-known and commonly used tool in those in the field of the present invention. Accordingly, the level of guidance necessary is low, and Applicant has provided more guidance regarding development of an algorithm of the claimed invention than would likely even be necessary to practice the invention.

3. The Presence or Absence of Working Examples

The Examiner further did not take into account the presence of working examples. A specification does not even need to contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue experimentation. MPEP 2164.02. Further, the presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure. "To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of claims." MPEP 2164.02. Here, Applicant has provided several working examples of the algorithm and has provided a description of the method taken to arrive at those working examples, which may be used to arrive at similar algorithms. The Examiner has only stated

> [T]he amount of light at each wavelength is one that has been corrected for atmospheric haze and sensor additive offset. Clearly the algorithms used in the instant claims are limited solely to algorithms derived in such a manner, where the amount of light is corrected. There is lack of guidance for determining suitable algorithms in any other manner, and this in turn results in a great amount of experimentation to apply numerous mathematical modeling techniques.

Examiner has not stated why one would not expect to be able to extrapolate the example provided by Applicant across the entire scope of claims. Applicant submits that by providing working examples, it has met the enablement requirement for the entire scope of the claims.

4. The Nature of the Invention

The nature of the invention necessarily involves linear regression analysis which must be applied to data collected in order to arrive at a robust algorithm. "The

specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public." MPEP 2163.05(a). Applicant states that the specification is enabling if the nature of the invention is taken into account. As noted throughout, linear regression analysis and modeling is a well-known and commonly used tool in the art, and Applicant respectfully submits that for this reason, the specification is enabling.

5. The State of the Prior Art, The Relative Skill of Those in the Art, and The Predictability of the Art

Applicant submits that the Examiner did not address these factors in the analysis, and had they been addressed, the specification would have been deemed enabling. Applicant submits that the state of the prior art and the relative skill of those in the art suggest that proper guidance is provided in the specification to enable one skilled in the art to practice the invention. Applicant submits that linear regression is a predictable method used by those skilled in the field of remote imaging. Further, the specification need not describe how to make and use every possible variant of the claimed invention, "for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments." *AK Steel Corp. v. Sollac*, 344 F. 3d 1234, 1244 (Fed. Cir. 2003). Accordingly, Applicant submits that these factors weigh in favor of the determination that the specification is enabling and that no undue experimentation is necessary.

6. The Breadth of the Claims

"The Examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole." MPEP 2164.08. Here, Applicant respectfully submits that its claims are properly enabled when viewed as a whole. Specifically, the specification teaches those skilled in the art how to make and use the full scope of the claimed invention, as required under MPEP 2164.08. All that is required is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. MPEP 2164.08. Here, Applicant submits that there is more than even just a "reasonable correlation" to the scope of the claims with the enablement of the specification. The specification provides clear guidance as to how linear regression may be performed to arrive at an algorithm claimed in the application. The fact that the claims cover an algorithm involving two spectral ratios or three or more spectral ratios does not automatically make them so broad so as to not be enabled by the specification.

In conclusion, Applicant submits that the Examiner has not provided a reasonable explanation as to why the specification is not enabling and further has not properly addressed all the *In Re Wands* factors to be considered in determining enablement. As explained above, Applicant has provided a specification which clearly teaches and describes the development of such an algorithm as described in claims 1-19 and 94-111, such that the full scope of the invention as reflected in the currently pending claims is fairly enabled without need for undue experimentation. Though some experimentation may be necessary to arrive at the proper algorithm, Applicant submits that the Examiner has not shown how such experimentation would be undue.

Accordingly, the initial burden of contesting the enablement of the specification has not been met.

## CONCLUSION

In view of the foregoing amendment and accompanying remarks, Applicant respectfully submits that the present application is properly in condition for allowance and may be passed to issuance upon payment of the appropriate fees.

Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the subject application is respectfully encouraged.

Respectfully submitted,

Date: Sept. 22, 2011 By: _____

Roger A. Gilcrest
Registration No. 31,954
Schottenstein, Zox & Dunn Co., L.P.A.
250 West Street
Columbus, Ohio 43215
P: (614) 462-1055
F: (614) 222-3437
Email: rgilcrest@szd.com